

CLAIMS

1. An oncology microarray comprising a plurality of samples, each sample stably associated with a distinct, known sublocation on a substrate, at least one sample comprising abnormally proliferating cells, the substrate further comprising an identifier providing access to a database comprising information relating to at least one patient from whom at least one sample was obtained.

5

2. The microarray according to claim 1, wherein said identifier, when entered into the interface of a user computer connectable to the network, causes a screen to be displayed displaying one or more links to portions of the database comprising information relating to said at least one patient.

10

3. An oncology microarray comprising a plurality of samples, each sample stably associated with a distinct, known sublocation on a substrate, at least one sample comprising abnormally proliferating cells, and at least one sample comprising frozen cells or tissue.

15

4. An oncology microarray comprising a plurality of samples, each sample stably associated with a distinct, known sublocation on a substrate, at least one sample comprising abnormally proliferating cells, and at least one other sample comprising cells from a bodily fluid from the same patient providing the sample of abnormally proliferating cells.

20

5. The microarray according to any of claims 1, 3, or 4, wherein at least one sample comprises normally proliferating cells.

6. The microarray according to any of claims 1, 3, or 4, comprising at least one sample selected from the group consisting of cancerous breast tissue, cancerous prostate tissue, cancerous colon tissue, cancerous cervical tissue, skin cancer, and cancerous lung tissue.

25

7. The microarray according to any of claims 1, 3, or 4, wherein at least about 10% of the samples of the microarray are from different tissue types.

8. The microarray according to any of claims 1, 3, or 4 comprising samples from at least about five different tumor types.

10. The microarray according to any one of claims 1, 3 or 4, wherein at least one sample is greater than about 0.6 mm in diameter.

10. The microarray according to claim 3, further comprising at least one sample comprising paraffin- or plastic-embedded cells or tissue.

5 11. The microarray according to any of claims 1, 3 or 4, comprising a plurality of samples representing different grades or stages of a single type of cancer.

12. The microarray according to claim 11, wherein said cancer is selected from the group consisting of breast cancer, skin cancer, head and neck cancer, colon cancer, cervical cancer, ovarian cancer, prostate cancer, and lung cancer.

10. 13. The microarray according to claim 1, 3, or 4, comprising a least one sample which comprises substantially homogeneous cells.

14. The microarray according to claim 13, wherein the at least one sample which comprises substantially homogeneous cells comprises cells which express a cancer-specific marker.

15. 15. The microarray according to any of claims 1, 3, or 4, wherein at least one sample is from a patient treated with a drug.

16. 16. The microarray according to any of claims 1, 3, or 4, wherein at least one sample is from a site of secondary metastasis of a cancer.

20 17. 17. A kit comprising:
(a) an oncology microarray, said oncology microarray comprising a plurality of samples, each sample stably associated with a distinct, known sublocation on a substrate, at least one sample comprising abnormally proliferating cells; and

25 (b) a normal tissue microarray, comprising at least two samples each of at least about two different tissue types.

18. 18. A kit according to claim 17, wherein said normal tissue microarray comprises at least about five different tissue types.

5 19. The kit according to claim 18, wherein said five different tissue types are selected from the group consisting of cerebrum, cerebellum, medulla, cardiac tissue, lung tissue, thyroid gland, adrenal gland, submandibular gland, pancreas, liver, tonsil, spleen, lymph node, endometrium, ovary stroma, myometrium, fallopian tube, endocervix, ectocervix, placenta, kidney, prostate, seminal vesicle, stomach tissue, duodenum, ileum, appendix, colon, gall bladder, skeletal muscle, and smooth muscle.

10 20. The kit according to claim 18, wherein said at least about five different tissue types are from a single patient.

15 21. The kit according to claim 18, wherein said normal tissue microarray comprises at least about ten different tissue types.

22. The kit according to claim 21, wherein said normal tissue microarray comprises at least about twenty different tissue types.

23. The kit according to claim 22 wherein said oncology array or said normal array further comprises an identifier providing access to a database comprising information relating to at least one patient from whom at least one sample was obtained.

24. The kit according to claim 23, wherein said identifier, when entered into the interface of a user computer connectable to the network, causes a screen to be displayed displaying one or more links to portions of the database comprising information relating to said at least one patient.

20 25. The kit according to claim 24, wherein said oncology microarray further comprises at least one sample comprising frozen cells or tissue.

26. The kit according to claim 24, wherein said oncology microarray further comprises at least one other sample comprising cells from a bodily fluid from the same patient providing the sample of abnormally proliferating cells.

25 27. The kit according to claim 24, wherein said oncology microarray comprises cells from abnormally proliferating head and neck tissue.

28. The kit according to claim 27, wherein said oncology microarray comprises one or more of
normal oral mucosa, cancerous oral mucosa with mild to moderate dysplasia, oral mucosa
with severe dysplasia or carcinoma in situ, nodal negative head and neck cancer, nodal
positive head and neck cancer, and lymph node metastases.

5 29. The kit according to claim 27, wherein said oncology microarray comprises one or more
samples comprising cancers of the lip, tongue, tonsil, oral mucosa, and pharynx.

30. The kit according to claim 24, wherein said oncology microarray comprises one or more
samples from tissues comprising benign prostatic hyperplasia, prostatic intraepithelial
neoplasia, prostate cancer (Gleason score 1-2), prostate cancer (Gleason score 4), prostate
10 cancer (Gleason score 5), and prostate cancer metastases.

31. The kit according to claim 24, wherein said oncology microarray comprises one or more
samples from normal colon tissue, cancerous colon mucosa, adenocarcinoma with mild
dysplasia, adenoma with severe dysplasia, nodal negative colorectal cancer, nodal positive
colorectal cancer, and colon cancer metastases.

15 32. The kit according to claim 24, comprising one or more samples from normal lung
parenchyma, normal lung bronchi, adenocarcinoma, squamous cell carcinoma,
undifferentiated large cell carcinoma, and metastases from cancerous lung tissue.

33. The kit according to claim 24, wherein said oncology microarray comprises one or more
normal breast tissue, ductal carcinoma tissue, invasive ductal tissue grade 1, invasive ductal
20 tissue grade 2, invasive ductal breast cancer grade 3, and metastases thereof.

33. The kit according to claim 24, wherein said oncology microarray comprises tissue samples
from at least five different tumor types.

34. The kit according to claim 33, where said tumor types are selected from the group consisting
of colorectal tumors, prostate tumor, lung tumors, breast tumors, kidney tumors, urinary
25 bladder tumors, ovarian tumors, brain tumors, malignant melanoma, and head and neck
tumors.

35. A method for detecting the expression of a cancer-specific marker in a test sample,
comprising:

(a) providing a test sample comprising cells or tissue;

(b) providing a microarray according to any of claims 1, 3, or 4, wherein said at least one sample comprising abnormally proliferating cells express said cancer-specific marker;

(c) reacting the test sample and the microarray with a molecular probe which specifically reacts with said cancer-specific marker;

(d) detecting the presence, absence or amount of said reactivity in said test sample and comparing said reactivity to the reactivity of said at least one sample.

36. The method according to claim 35, wherein said comparing in step (d) provides a diagnosis or prognosis of cancer in cells or tissue in said test sample.

37. The method according to claim 36, wherein information relating to the reactivity of said molecular probe with said test sample and/or said microarray is entered into a specimen-linked database.

38. The method according to claim 35, wherein said test sample is from a patient treated with a drug.